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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,459	11/12/2003	Eilon Barnea	26884	8318

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,459	BARNEA ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 2-3, 6 and 27, drawn to a method of identifying peptides originating form a particular cell type and being capable of binding to MHC molecules of a particular haplotype, comprising obtaining a cell expressing *a soluble and secreted form of the MHC molecule*, wherein the cell type is a cancer cell or cell line, classified in Class 435, subclass 7.23.

II. Claims 4, 6 and 29, drawn to a method of identifying peptides originating form a particular cell type and being capable of binding to MHC molecules of a particular haplotype, comprising obtaining a cell expressing *a soluble and secreted form of the MHC molecule*, wherein the cell type is a virus infected cell or cell line, classified in Class 435, subclass 7.1.

III. Claims 5, 6 and 28, drawn to a method of identifying peptides originating form a particular cell type and being capable of binding to MHC molecules of a particular haplotype, comprising obtaining a cell expressing *a soluble and secreted form of the MHC molecule,* wherein the cell type is a cell involved in a development and/or progression of an autoimmune diseases, classified in Class 435, subclass 7.24.

IV. Claims 9-10, 25, 31-32, drawn to an electronic data storage device, storing, in a retrievable form, a polarity of sequences of peptide, classified in Class 703, subclass 11.

V. Claims 11-15, drawn to a kit comprising a plurality of individual containers each containing at least one peptide identified by claim 1; classified in Class 435, subclasses 810 and 975.

VI. Claims 16-24, drawn to a method of identifying peptides originating from at least one protein of interest and being capable of binding to MHC molecules of a particular haplotype comprising obtaining *cells co-expressing the at least one protein of interest and a soluble and secreted form of the MHC molecules* of the particular hapalotpe, classified in Class 435, subclass 7.24.

VII. Claim 26, drawn to a kit comprising a plurality of individual containers each containing at least one peptide identified by claim 16, classified in Class 435, subclasses 810 and 975.

VIII. Claim 30, drawn to a method of identifying peptides originating from a particular cell type characterized by cell over-expressing at least one protein, the peptides being capable of binding to MHC molecules of a particular haplotype, comprising obtaining

cells of the partiucla rcell type expressing a soluble and secreted form of the MHC molecules of the particular haplotype, classified in Class 435, subclasses 7.1.

IX. Claim 30, drawn to a method of identifying peptides originating from a particular cell type characterized by cells characterized by induced mutations, the peptides being capable of binding to MHC molecules of a particular haplotype, comprising obtaining cells of the partiucla rcell type expressing a soluble and secreted form of the MHC molecules of the particular haplotype, classified in Class 435, subclasses 7.1.

X. Claim 30, drawn to a method of identifying peptides originating from a particular cell type characterized by cells of metastases, the peptides being capable of binding to MHC molecules of a particular haplotype, comprising obtaining cells of the partiucla rcell type expressing a soluble and secreted form of the MHC molecules of the particular haplotype, classified in Class 435, subclasses 7.1.

XI. Claim 30, drawn to a method of identifying peptides originating from a particular cell type characterized by normal or transformed cells expressing cell surface proteins, the peptides being capable of binding to MHC molecules of a particular haplotype, comprising obtaining cells of the partiucla rcell type expressing a soluble and secreted form of the MHC molecules of the particular haplotype, classified in Class 435, subclasses 7.1.

XII. Claim 30; drawn to a method of identifying peptides originating from a particular cell type characterized by at least one of the following (i) cell over-expressing at least one protein; (ii) cells characterized by induced mutations, (iii) cells of metastases; (iv) normal or transformed cells expressing cell surface proteins [**please specify a combination, each combination is a GROUP**], the peptides being capable of binding to MHC molecules of a particular haplotype, comprising obtaining cells of the partiucla rcell type expressing a soluble and secreted form of the MHC molecules of the particular haplotype, classified in Class 435, subclasses 7.1.

XIII. Claims 33-36 and 50, drawn to a method of eliciting an immune response against a protein of interest in a subject having a particular MHC haplotpe comprising determining the subject's particular MHC haplotpe and administering to the subject an effective amount of at least one peptide derived from the protein of interest, classified in Class 424, subclass 185.1.

XIV. Claims 37-49 and 51-71, drawn to a peptide and a composition thereof, classified in Class 530, subclasses 324-330

Note Absent evidence to the contrary, each of the recited peptide sequences is distinct since each peptide is derived form different protein of interest and is not obvious over the other set of peptides. Therefore the instant claims 37-49 and 51-71 encompass hundreds of GROUPS, not species.

Claims 1 and 7-8 link inventions I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims 1 and 7-8. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. Groups IV-V, VII and XIV are different products. Kits, electronic data storage device and peptides with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups I-III, VI and VIII-XIII are different methods. Various methods of identifying and a method of eliciting/treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group V or XIV is elected, applicant is required to elect a single specific modification such as a) peptoid modification, b) semipeptoid modification, c) cyclic peptide modification, d) N terminus modification, e) C terminus modification, f) peptide bond

modification, g) backbone modification or h) residue modification. These modifications are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 19, 2006

Maher Haddad

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